K131483
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PHILIPS

5. 510(k) Summary

Type of submission: Traditional 510(k)

Date of Submission: Hamburg, 13 May 2013 Original Submission Date

Name and Address of Manufacturer and 510(k) Owner:

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Device Identification

OCT 07 2013

Trade Name:	Philips *Pixium 4343RC*
Model number:	PX4343RC
Common names:	Stationary X-Ray System
Classification(s) of the device:	Stationary X-Ray System, 21CFR 892.1680, Product Code: MQB, Classification Panel: 90 – Radiology, Class II

Equivalent legally marketed devices:

Philips BuckyVision, K982795 (introducing the *Trixell Pixium 4600* Stationary Solid State X-ray Imager). The BuckyVision system is also marketed under the commercial name of *Digital Diagnost*.

Philips Wireless Portable Detector FD-W17, K090625

Device Description:

The *Pixium 4343RC* is a Solid State X-ray Imaging Device that converts x-ray patterns into electrical signals. The signals are converted into visible images for use in medical diagnosis. In the device, a cesium iodide scintillator absorbs the input x-ray photons. The scintillator in turn emits visible spectrum photons that illuminate an array of photodetectors that create an electrical charge representation of the x-ray input. A matrix scan of the array converts the integrated charges into a modulated electrical signal.

The detector is permanently installed and intended to be integrated into an x-ray system, where it constitutes an x-ray receptor for direct x-ray imaging. It is electrically powered and connected with the x-ray system. The device is connected to the Philips *XD-S Eleva Radiography Workstation* to create a complete x-ray imaging chain, and it is intended to be used exclusively in the Philips *Digital Diagnost* x-ray system, one of the predicate devices.

- Detector Size: 500 x 490 x 45.5 mm^3
- Image Size (Pixel): 2840 x 2874
- Pixel Size: 148 µm
- Image Resolution up to 3.4 LP/mm

An identical Solid State X-Ray Imager has received pre- market clearance, under K123005 (December 7, 2012), for use with the Swissray medical AG x-ray system.

Intended Use:

The Indication for Use for the Philips *Pixium 4343RC* is identical to that of the predicate, the Wireless Portable Detector FD-W17 and is as follows:

As a part of a radiographic system, the *Pixium 4343RC* is intended to acquire digital radiographic images. The *Pixium 4343RC* is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammography.

The Philips BuckyVision System (K982795) is a radiography system introducing a *Pixium 4600* Solid State X-Ray Imager. The Philips Wireless Portable Detector FD-W17 (K090625) is a typical digital radiography imaging chain consisting of a Solid State X-Ray Imager, and the image processing software XD-S Eleva Workstation that has received pre-market clearance under the pre-market notification number K06371. The Philips Wireless Portable Detector FD-W17 is cleared for use with the Philips BuckyVision System, along with clearance for use with other Philips Radiography Systems. The Philips *Pixium 4343RC* is a typical digital radiography imaging chain consisting of a Solid State X-Ray Imager *Pixium 4343RC* and the image processing software XD-S Eleva Workstation. The x-ray imager *Pixium 4343RC functions* equivalently to the *Pixium 4600* solid state x-ray detector in the BuckVision System.

This is the first Philips 510(k) Premarket Notification for the Philips *Pixium 4343RC*, and there have been no previous Philips submissions for the Philips *Pixium 4343RC*;

however, an identical detector (*Pixium 4343RC*) has received pre- market clearance by Swissray Medical AG for use with their x-ray system, under pre-market notification number K123005, issued in December of 2012.

Summary of technological characteristics / non-clinical testing and performance data:

This modified device has the same indications for use and technological characteristics as the predicate devices. Comparisons of the following technological characteristics, and non-clinical performance data (indicated by *), were assessed, and the results demonstrate the substantial equivalence to the predicates:

	Predicate Device: Pixium 4600 Detector	***Predicate Device: FD-W17***	***New Device: Pixium 4343RC***	***Discussion***
510(k) Number	K982795 (Philips BuckyVision also known as the Digital Diagnost)	K090625 (Philips Wireless Portable Detector FD-W17)	N/A	N/A
Description	Detector, part of Philips Digital Diagnost (previously "Bucky Vision")	Detector, part of Philips Digital Diagnost (previously "Bucky Vision")	Detector, part of Philips Digital Diagnost (previously "Bucky Vision")	Identical
Device Type	Solid State X-Ray Imager (MQB)	Solid State X-Ray Imager (MQB)*	Solid State X-Ray Imager (MQB)	Identical
510(k) Owner	Philips Medical Systems DMC, Hamburg, Germany	Philips Medical Systems DMC, Hamburg, Germany	Philips Medical Systems DMC, Hamburg, Germany	Identical
Indications for Use	The Philips Bucky Vision is intended for use in general radiographic examinations and applications wherever conventional screen-film systems may be used (excluding fluoroscopy, angiography, and mammography)	As a part of a radiographic system, the Wireless Portable Detector FD-W17 is intended to acquire digital radiographic images. The Wireless Portable Detector FD-W17 is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work,	As a part of a radiographic system, the *Pixium 4343RC* is intended to acquire digital radiographic images. The *Pixium 4343RC* is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammography.	Identical / Equivalent

	Predicate Device: Pixium 4600 Detector	***Predicate Device: FD-W17***	***New Device: Pixium 4343RC***	***Discussion***
		excluding fluoroscopy, angiography and mammography.		
X-Ray Absorber	CsI Scintillator	CsI Scintillator	CsI Scintillator	Identical
Installation type	Stationary, permanently installed	Portable	Stationary, permanently installed	Identical
Readout Mechanism	Switching Diode	Thin Film Transistor	Thin Film Transistor	Equivalent
Detector Size	533 x 488 x 45.5 mm^3	489 x 466 x 25 mm^3	500 x 490 x 45.5 mm^3	Equivalent
Detector Weight	17.8 kg	<5.1 kg	<14 kg	Equivalent
Image Size (Pixel)	3001 x 3001	3000 x 2400	2840 x 2874	Equivalent
Image Size (X-ray field)	429 x 429 mm^2	432 x 341.1 mm^2	420 x 425 mm^2	Equivalent
Distance Image to Rim	27.5 mm	28.2 mm	34.9 mm	Equivalent
Pixel Size	143 µm	144 µm	148 µm	Equivalent
Nyquist Frequency:	3.50 lp/mm	3.47 lp/mm	3.37 lp/mm	Equivalent
ADC Digitisation	14 bit	16 bit	16 bit	Equivalent
Maximum X-ray Dose for Linear Response	30 µGy	50 µGy	50 µGy	Equivalent
Maximum Usable Dose	60 µGy	75 µGy	85 µGy	Equivalent
Number of Modes	5	1	2	Equivalent
Exposure Window Durations	0.5 s, 1.0 s, 2.0 s, 3.2 s, 4 s	1-8192 ms	1-8192 ms	Equivalent
Image Data	19.24 MBytes	14.4 MBytes	16.3 MBytes	Equivalent
Scintillator	500 µm CsI(Tl), glued	500-600 µm CsI(Tl), glued	500-600 µm CsI(Tl), glued	Equivalent
Use w and w/o Radiographic Grid?	Yes	Yes	Yes	Identical
Maximum	100 Gy	100 Gy	100 Gy	Identical

	Predicate Device: Pixium 4600 Detector	***Predicate Device: FD-W17***	***New Device: Pixium 4343RC***	***Discussion***
Lifetime Dose				
Warm-up Duration before Calibration	4 h	2 h	4 h	Identical
Digital Subtraction Angiography (DSA)	None (exempt from intended use)	None (exempt from intended use)	None (exempt from intended use)	Identical
Positioning Mode	None	None	None	Identical
Stitching Mode (Implemented in Detector)	None	None	None	Identical
Binning	None (1 x 1)	None (1 x 1)	None (1 x 1)	Identical
Framespeed: Dynamic Imaging – Pulsed	None	None	None	Identical
Data Interface to Workstation	Taxi	100 Mbit/s Ethernet	100 Mbit/s Ethernet	Equivalent
Power Consumption	18 W	10 W	20.4 W	Equivalent
Modulation Transfer Function (MTF)	1 lp/mm 62% 2 lp/mm 33% 3 lp/mm 17% 3.4 lp/mm *13%*[1] 3.5 lp/mm 12% (Nyquist)	1 lp/mm 60% 2 lp/mm 30% 3 lp/mm 15% *3.4 lp/mm 13%*† 3.5 lp/mm 12% (Nyquist)	1 lp/mm 64% 2 lp/mm 32% 3 lp/mm 17% 3.4 lp/mm 13% (Nyquist)	Equivalent
Detective Quantum Efficiency (DQE)	DQE at 1 µGy 1 lp/mm 50% 2 lp/mm 40% 3 lp/mm 23% 3.4 lp/mm *17%*† 3.5 lp/mm 15%	DQE at 2.5 µGy 0.05 lp/mm 66% 1 lp/mm 51% 2 lp/mm 39% 3 lp/mm 22% *3.4 lp/mm 15%*† 3.5 lp/mm 13%•	DQE at 1 µGy 0.05 lp/mm 65% 1 lp/mm 51% 2 lp/mm 42% 3 lp/mm 25% 3.4 lp/mm 18%	Equivalent
Image Processing	Philips Thoravision (510(k) Number: K931071)	*XD-S Eleva Workstation* (previously "*XD-S Direct Workstation/Package*") (510(k) Number: K063781)	*XD-S Eleva Workstation* (previously "*XD-S Direct Workstation/Package*") (510(k) Number: K063781)	Identical

[1] Linear approximation to facilitate direct comparison.

	Predicate Device: Pixium 4600 Detector	***Predicate Device: FD-W17***	***New Device: Pixium 4343RC***	***Discussion***
Grid line suppression	Mechanical Grid Oscillation	Mechanical Grid Oscillation or Image Pre-Processing ("*Grid Suppression*")	Mechanical Grid Oscillation or Image Pre-Processing ("*Grid Suppression*")	Identical

Note: Table entries identified by grey cell shading are stated for reference purposes only.

Description of Clinical Testing

A concurrence study according to CDRH's *Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices* was conducted, and the study confirmed that the Philips *Pixium 4343RC* integrated with the Philips Bucky System provides images of equivalent diagnostic capability to the predicate radiographic system, the Philips BuckyVision integrated with the *Trixell Pixium 4600* Stationary Detector, and its results demonstrate substantial equivalence.

Guidance Discussion

All applicable and identified requirements provided in the used guidance documents

- *Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices*
- *Format for Traditional and Abbreviated 510(k)*
- *Pediatric Information for X-ray Imaging Device Premarket Notifications, Draft*
- *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*
- *Refuse to Accept Policy for 510(k)s*

demonstrate substantial equivalence.

The modified device conforms to the following US recognized consensus standards for safety for medical devices:

- ANSI/AAMI ES 60601-1:2005/(R)2012 and C1:2009/(R)2012 - *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*[2]
- IEC 60601-1-2 Edition 3:2007-03 - *Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests*[‡]

[‡] NRTL certified compliance

- ISO 14971 Second edition 2007-03-01 - Medical devices - Application of risk management to medical devices
- IEC 60601-1-3 Edition 2.0 2008-01 - *Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment*
- IEC 62304 First edition 2006-05 - Medical device software - Software life cycle processes
- IEC 60601-2-54 Edition 1.0 2009-06 - *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography ad radioscopy*
- IEC 62220-1 Edition 1.0 (2003-10) - *Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency*

Conclusion:

The comparison of technological characteristics, non-clinical performance data, safety testing, software validation, and clinical image concurrence data demonstrates that the device is as safe, as effective, and performs as well or better than the predicate devices.

Philips Medical Systems concludes that the device is substantially equivalent to the currently legally marketed predicate devices. The *Pixium 4343RC* does not introduce new indications for use or intended use, has identical or equivalent technological characteristics, provides images of equivalent diagnostic capability, and does not introduce new potential hazards or safety risks. The device is as safe, as effective, and performs as well or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 7, 2013

Philips Medical Systems DMC GmbH
% Ms. Jennifer Cartledge
REU Associates, Inc.
409 Woodridge Drive
SENECA SC 29672

Re: K131483
Trade/Device Name: Philips Pixium 4343RC
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 27, 2013
Received: September 9, 2013

Dear Ms. Cartledge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K131483

Device Name: Philips *Pixium 4343RC* Model: *4343RC*

Indications For Use:

As a part of a radiographic system, the *Pixium 4343RC* is intended to acquire digital radiographic images. The *Pixium 4343RC* is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammography.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131483